

POLICY: Technical Consultant Qualifications and Responsibilities

DEPARTMENT: Red Cliff Health Center Laboratory

PROCEDURE:

1. The laboratory must have a technical consultant qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties tested in the laboratory. The qualifications include:
 - A. Possess a current license issued by the state in which the laboratory is located
AND
 - B. Hold a doctoral or master's degree in a chemical, physical, biological, or clinical laboratory science or medical technology from an accredited institution, and have at least one year of laboratory training or experience or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.
OR
 - C. Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution, and have at least two years of laboratory training or experience or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.
OR
 - D. Be a doctor of medicine or osteopathy licensed to practice medicine or osteopathy in the state in which the laboratory is located and be certified in anatomic, clinical pathology, or both by the American Board of Pathology or the American Osteopathic Board of Pathology, or possess qualifications that are equivalent.
OR
 - E. Be a doctor of medicine, osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the state in which the laboratory is located, and have at least one year of laboratory training or experience or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.

2. In order to ensure the laboratory's Technical Consultant is performing each of the responsibilities outlined in CLIA's regulations, the Laboratory Director will perform a semiannual review for any new consultant as well as an annual review for consultants after the first year of hire sometime during the last quarter of the fiscal year (June 1- September 30).
 - A. The performance review will consist of the Laboratory Director completing the Technical Consultant Responsibilities Checklist found in the Laboratory's Policy and Procedure manual as well as signing and dating the document.
 - B. If the laboratory director finds any deficiencies with the review, the consultant will need to report directly to the Laboratory Director on a monthly basis until the deficiencies are resolved. If the deficiencies continue, disciplinary actions may be taken.

Policy Date: July 2014

Amy Koenamann

Policy Analyst

Technical Consultant Responsibilities Checklist

- ☐ The technical consultant is responsible for the technical and scientific oversight of the laboratory.
- ☐ The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation.
- ☐ The technical consultant must be accessible to the laboratory to provide on-site, telephone, or electronic consultation.
- ☐ Selection of test methodology appropriate for the clinical use of the test results.
- ☐ Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.
- ☐ Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered.
- ☐ Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results.
- ☐ Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications.
- ☐ Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly.
- ☐ Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed.
- ☐ Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--

- ☐ Direct observations of routine patient test performance which includes: patient preparation (if applicable) specimen handling, processing and testing as well as monitoring the recording and reporting of test results.
- ☐ Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.
- ☐ Direct observation of performance of instrument maintenance and function checks.
- ☐ Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.
- ☐ Assessment of problem solving skills
- ☐ Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes. In which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

LABORATORY DIRECTOR'S SIGNATURE: _____ **DATE:** _____

TECHNICAL CONSULTANT'S SIGNATURE: _____ **DATE:** _____